

thermo scientific



## Nalgene carboys for bulk storage of drugs and reagents

Superior containers to maximize product security

**ThermoFisher**  
SCIENTIFIC

# All carboys are not created equal

Thermo Scientific™ Nalgene™ containers are made with high-quality resins that meet pharmaceutical, laboratory, and food grade standards. That's why millions of Nalgene carboys and bottles are at work in bioproduction facilities and laboratories around the world. Choose from a wide range of quality carboys and jerricans to fit your application requirements—from collecting and mixing reagents, media, and bulk vaccines to storing active pharmaceutical ingredients.

## Trust the proven performance of Nalgene containers

When selecting carboys for critical bioproduction applications, standard laboratory carboys fall far short of what is required for this highly regulated industry. We provide the necessary application support and documentation, as well as a robust customer notification process. Customization with fluid transfer options and presterilized carboys are additional benefits you can expect from the Thermo Scientific™ Nalgene™ portfolio. Thermo Scientific™ Nalgene™ containers are made with

high-quality resins, and meet the rigorous pharmaceutical production, laboratory and foodgrade standards. Our resins are selected to minimize additives and reduce potential leachables. We do not use plasticizers or fillers, and our plastics have low total ash content—a measure of impurities.

## Nalgene carboys minimize risk, protecting your valuable products

- Leakproof\* to help ensure contained materials are not lost during storage or transport
- Sterile, single-use options to eliminate the need for in-house packaging and sterilization
- Container designs that enable cleaning validations
- Sanitary fitting options for easier cleaning validations and processes
- Validation binders and forced extraction studies to support regulatory compliance



Shatter-resistant plastic containers are less likely to break than glass. The high-quality materials and construction of Nalgene containers enhance this advantage, assuring protection for your valuable products.

\* Our guarantee for a leakproof seal is subject to our standard product warranty, as set forth in the Thermo Fisher Scientific Terms and Conditions of Sale. Our products are leakproof at ambient temperature and pressure when used with their corresponding closures. However, to ensure safe usage, customers are advised to test our containers and closures under conditions of their planned applications.

# Our leakproof guarantee

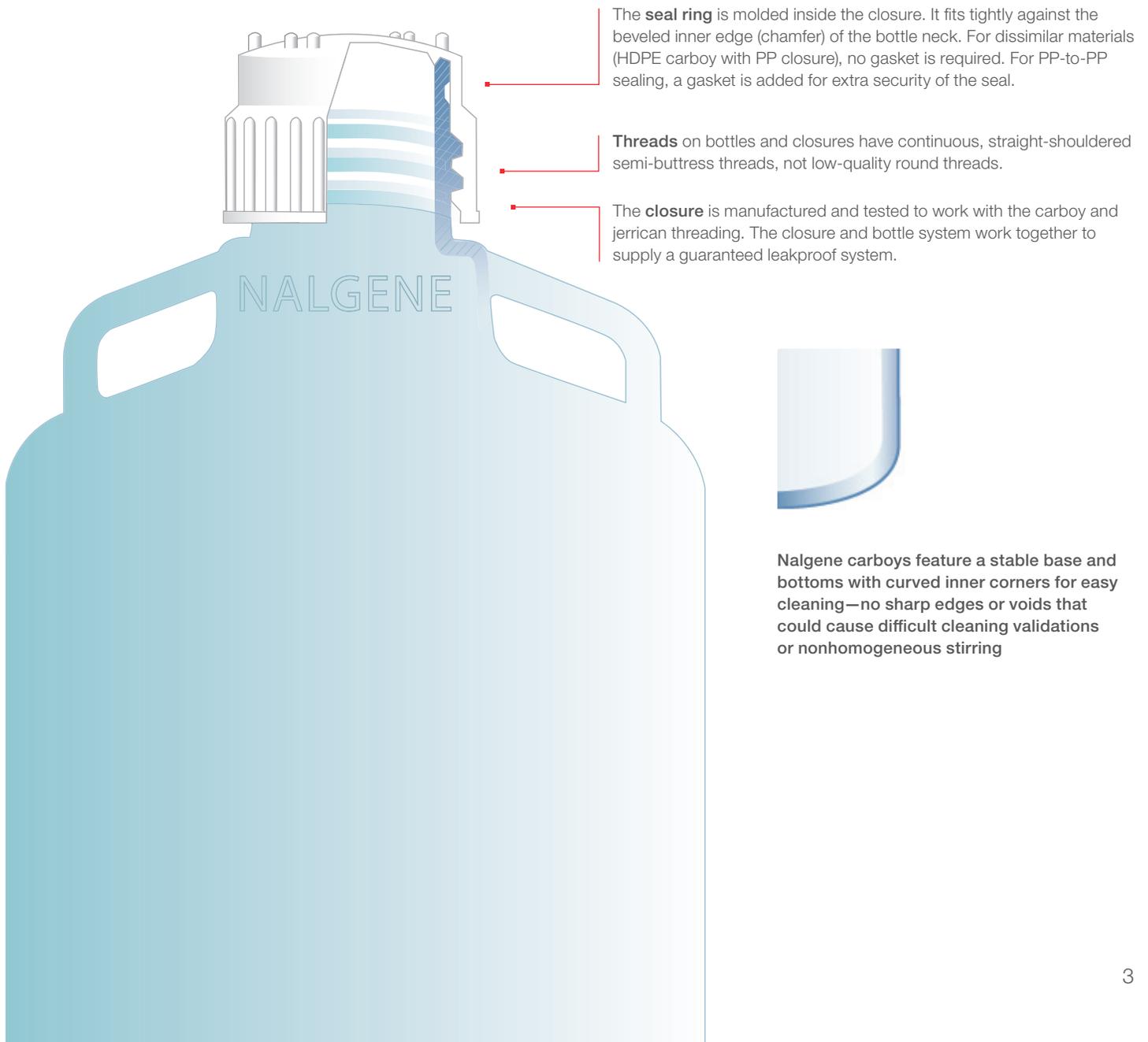
## We stand behind every Nalgene carboy and jerrican you buy

Nalgene carboys and closures are engineered to work together with a strong, semi-buttress thread design that prevents stripping. We offer a leakproof guarantee because we manufacture and test both components together as part of our routine quality inspection process (see page 15 for details).

If any Nalgene container doesn't meet our leakproof standards, simply return it to us and we will replace it—guaranteed.

## Anatomy of a Nalgene carboy

Nalgene carboys and closures are designed, manufactured, and supported with the rigorous needs of the pharmaceutical and biologics markets in mind.



# Forced extraction study reports

The qualification and validation of production, harvest, and containment supplies is an integral part of any biopharmaceutical application process. Regulatory guidelines around the world recommend that the production, storage, and packaging components are assessed for extractables or leachables that may interact with or impact the product being manufactured.

To support you, we commissioned studies to identify compounds that may be extracted from key components under extreme conditions, and to estimate the quantity of these compounds. These studies are designed to guide you to choose the correct container to show what typical extractable and leachables may be expected when conducting your own studies for submission.

Combined with NIST98K, Wiley, and other databases, these techniques provide the information required to profile and identify any significant extractables from each component tested. The evaluation of extractables is based on the semi-quantitative estimation of analytes obtained by these techniques.

An analysis protocol is available for review upon request under a confidential disclosure agreement (CDA), defining the strategy utilized to perform the extraction process.

# 1

**Studies were conducted on two different Nalgene carboys systems:**

- Nalgene PP carboys and closures (TPE gasket and PP white closure)
- Nalgene sterile HDPE carboys and closures (PP white closure)

# 2

**Three extraction solvents were used on each unit for the forced extraction process:**

- Water
- Ethanol\*
- Hexanes\*
- 10% nitric acid\*\*

\* Direct injection GC/MS and LC/MS analysis.

\*\* ICP/OES analysis only.

# 3

**Each extracted solution was subsequently analyzed by:**

- Headspace Gas Chromatography/Mass Spectrometry (GC/MS) for volatile and Direct Injection GC/MS for semi-volatile organic compounds
- Liquid Chromatography/Mass Spectrometry (LC/MS) for non-volatile organic compounds
- Inductively Coupled Plasma (ICP) for metals and elemental extractables using an acid-digested solution

In addition to forced extraction studies for the carboy systems, several other studies are available across the Nalgene storage solutions portfolio

### Forced extraction studies

Description	Cat. No.
Nalgene PETG Bottles (System, irradiated at 19-28 kGy)	105-0001
Nalgene PETG Bottles (System, irradiated at 20-45 kGy)	105-0010
Nalgene PC Biotainers Bottles (System, US Resin)	105-0002
Nalgene PP Carboys (System)	105-0003
Nalgene PETG Biotainers Bottles (System)	105-0004
Nalgene Sterile HDPE Carboys (System)	105-0007

### Understand the difference between extraction studies and the leachables studies

#### Extractables

These are chemical entities that migrate from any product contact material when exposed to an appropriate solvent under exaggerated conditions of time and temperature. The solvents and conditions are meant to be extremely aggressive and designed to represent “worst-case” results.

#### Leachables

Leachables consist of chemical compounds that are typically a subset of extractables that can migrate from the contact material into stored solutions under normal process conditions and/or accelerated conditions. Leachable studies are designed to produce results representative to actual application and use of the products.

For more information, contact us at [rocregsupport@thermofisher.com](mailto:rocregsupport@thermofisher.com)

For specific compliance needs, you may find the following guides helpful:

- FDA Guidance for Industry: Container Closure Systems for Packaging of Human Drugs and Biologics—Chemistry, Manufacturing, and Controls Documentation, May, 1999
- EMEA Guideline on Plastic Immediate Packaging Materials, CPMP/QWP/4359/03 and EMEA CVMP/205/04, European Medicines Agency, May, 2005



# High-density polyethylene (HDPE)

Ideal for harsh conditions where excellent chemical compatibility is required

- Leakproof PP screw-top design
- Wide range including heavy-duty for extra-aggressive conditions, amber for light-sensitive products, and wide-mouth design for easy filling and dispensing of liquids
- Round for homogeneous stirring
- Rectangular shape (jerrican) for efficient use of storage space
- Pre-sterilized, single-use options mean no in-house sterilizing or sterilization validation required
- Suitable for conditions from  $-100^{\circ}\text{C}$  to  $+120^{\circ}\text{C}$



## Recommended applications

Media formulation and mixing, aseptic protocols, aggressive conditions or chemicals, and production where products may adhere to and leach out of containers.

Description	Capacity, L (gal)	Dimensions			Height with closure, mm (in.)	No. per Pk/Cs	Cat. No.
		Closure size, mm	Length, mm (in.)	Width/OD, mm (in.)			
Single-Use Carboy	20 (5.3)	83B	—	284 (11.2)	502 (19.8)	1/6	342289-0050*
Single-Use Carboy, Molded-in Handles	33 (8.7)	83B	—	381 (15.0)	546 (21.5)	1/1	342289-0075
Amber Carboy	10 (2.6)	83B	—	250 (9.8)	383 (15.1)	1/6	2256-7020
Fluorinated Carboy	10 (2.6)	83B	—	250 (9.8)	389 (15.3)	1/6	2097-0020
Fluorinated Carboy	20 (5.3)	83B	—	282 (11.1)	526 (20.7)	1/4	2097-0050
Rectangular Carboy without Spigot	9 (2.4)	100-415	220 (8.7)	153 (6.0)	360 (14.2)	1/6	2211-0020
Rectangular Carboy without Spigot	20 (5.3)	100-415	320 (12.6)	229 (9.0)	399 (5.71)	1/4	2211-0050
Heavy-Duty Rectangular Carboy	20 (5.3)	70	330 (13.0)	228 (9.0)	406 (16.0)	1/4	2214-0050
Heavy-Duty Wide-Mouth Carboy	20 (5.3)	120	305 (12.0)	203 (8.0)	457 (18.0)	1/4	2241-0050**
Jerrican Tethered Angled Closure	6 (1.5)	53B	213 (8.4)	176 (6.9)	335 (13.2)	1/6	2240-0015
Jerrican Tethered Angled Closure	10 (2.6)	53B	246 (9.7)	199 (7.8)	376 (14.8)	1/6	2240-0025
Jerrican Tethered Angled Closure	20 (5.3)	53B	320 (12.6)	245 (9.6)	452 (17.8)	1/4	2240-0050
Jerrican Tethered Top Closure	13 (3.5)	53B	290 (11.4)	189 (7.4)	378 (14.9)	1/4	2243-0013
Jerrican Tethered Top Closure, 38 mm Spigot	13 (3.5)	53B, 38-430	290 (11.4)	189 (7.4)	378 (14.9)	1/4	2243-9013
Fluorinated Jerrican	10 (2.6)	53B	246 (9.7)	199 (7.8)	376 (14.8)	1/6	2242-0025
Fluorinated Jerrican	20 (5.3)	53B	320 (12.6)	245 (9.6)	452 (17.8)	1/4	2242-0050
<b>Accessories</b>							
Handle for 20 L Single-Use Carboy (Stainless Steel)						1/1	2229-0001
53B Replacement Closure and Strap for Jerrican						10/10	712240-1053
38-430 Replacement Closure for Large Nalgene Bottles						12/12	712160-0384
53B Replacement Closure for Large Nalgene Bottles or Carboys						12/12	712160-0530
83B Replacement Closure for Large Nalgene Bottles or Carboys						2/2	712160-0830

\* Handle must be purchased separately.

\*\* Designed for powder and solid storage; closure is not leakproof.

# Polycarbonate (PC)

## Excellent crystal-clear glass alternative

- Leakproof PP screw-top design
- Autoclavable for in-house sterilization
- Graduations for volume determination at a glance
- Crystal-clear like glass, yet fracture-resistant even at low temperatures
- Smaller validation sizes are available to save on expensive process validations
- Round for homogeneous stirring
- Rectangular shape (jerrican) for efficient use of storage space



### Recommended applications

Where full content visualization is required and for any protocol using glass where a safer alternative is required.

Description	Capacity, L (gal)	Closure size, mm	Dimensions			No. per Pk/Cs	Cat. No.
			Length, mm (in.)	Width/OD, mm (in.)	Height with closure, mm (in.)		
Round Clearboy	10 (2.6)	83B	—	253 (10.0)	394 (15.5)	1/4	2251-0020
Round Clearboy	20 (5.3)	83B	—	287 (11.3)	536 (21.1)	1/4	2251-0050
Rectangular Clearboy	9 (2.4)	100-415	220 (8.7)	153 (6.0)	360 (14.2)	1/1	DS2213-0020
Rectangular Clearboy	20 (5.3)	100-415	320 (12.6)	229 (9.0)	399 (15.7)	1/1	DS2213-0050
Validation Bottle	30 mL (1 oz.)	20-415	—	32 (1.3)	75 (3.0)	1/30	DS2127-0030
Validation Bottle	250 mL (8.5 oz.)	53B	—	74 (2.9)	135 (5.3)	1/6	DS2127-0250
Validation Bottle	2 (0.5)	53B	—	123 (4.8)	296 (11.7)	1/12	DS2127-2000
<b>Accessories</b>							
53B Replacement Closure for Large Nalgene Bottles or Carboys						12/12	712160-0530
83B Replacement Closure for Large Nalgene Bottles or Carboys						2/2	712160-0830
TPE Gasket for 53B Closure						12/12	712160-0053
TPE Gasket for 83B Closure						5/5	712162-1830

# Polypropylene (PP)

Ideal for in-house cleaning and autoclaving

- Leakproof PP screw-top design with TPE gasket
- Convenient shoulder or attached metal handles for easy carrying and pouring
- Graduations for volume determination at a glance
- Heavy-duty version for vacuum or extreme conditions
- Wide-mouth version for easy cleaning, filling and dispensing
- Version with sanitary dispensing port for use as supply reservoir
- Round shape for homogeneity during stirring
- Rectangular shape (jerrican) for efficient use of storage space



## Recommended applications

- Where autoclave-sterilization is required
- Vacuum or extreme use conditions (heavy-duty)
- Bulk API or other substances as reservoir for dispensing
- Solid or powder material storage (wide-mouth)

Description	Capacity, L (gal)	Dimensions			Height with closure, mm (in.)	No. per Pk/Cs	Cat. No.
		Closure size, mm	Length, mm (in.)	Width/OD, mm (in.)			
Rectangular Carboy with SS Handle	9 (2.4)	100-415	220 (8.7)	153 (6.0)	360 (14.2)	1/6	2212-0020
Rectangular Carboy with SS Handle	20 (5.3)	100-415	320 (12.6)	229 (9.0)	399 (15.7)	1/4	2212-0050
Heavy-Duty Carboy with Handles	10 (2.6)	83B	—	250 (9.8)	389 (15.3)	1/6	2226-0020
Heavy-Duty Carboy with Handles	20 (5.3)	83B	—	282 (11.1)	526 (20.7)	1/4	2226-0050
Wide-Mouth Carboy with Handles	10 (2.6)	100-415	—	250 (9.8)	343 (13.5)	1/6	2235-0020
Wide-Mouth Carboy with Handles	20 (5.3)	100-415	—	282 (11.1)	483 (19.0)	1/4	2235-0050
Carboy with Handles, Autoclavable	10 (2.6)	83B	—	250 (9.8)	389 (15.3)	1/6	2250-0020 8250-0020†
Carboy with Handles, Autoclavable	20 (5.3)	83B	—	282 (11.1)	526 (20.7)	1/4	2250-0050 8250-0050†
Carboy with Handles, Autoclavable	50 (13.2)	83B	—	379 (14.9)	678 (26.7)	1/1	2250-0130 8250-0020†
Carboy with Sanitary Flange Bottom, Autoclavable	10 (2.6)	83B, 1-1/2 in. Tri Clover	—	250 (9.8)	389 (15.3)	1/1	2640-0020
Carboy with Sanitary Flange Bottom, Autoclavable	20 (5.3)	83B, 1-1/2 in. Tri Clover	—	282 (11.1)	526 (20.7)	1/1	2640-0050
Carboy with Sanitary Flange Bottom, Autoclavable	50 (13.2)	83B, 1-1/2 in. Tri Clover	—	379 (14.9)	678 (26.7)	1/1	2640-0130
<b>Accessories</b>							
True Union Clamp for 1-1/2 in. Tri Clover						1/1	2670-0150
Gasket for 1-1/2 in. Tri Clover						6/6	2672-0150
83B Replacement Closure for Large Nalgene Bottles or Carboys						2/2	712160-0830
TPE Gasket for 83B Closure						5/5	712162-1830

† 8250-series products are manufactured in our state-of-the-art facility in Suzhou, China. All other products are manufactured in Rochester, New York.



## Autoclaving recommendations for Nalgene PC- or PP-based carboys

- The recommended autoclaving cycle is 121°C, 1 bar and/or 250°F, 15 psig for 15–20 minutes
- Avoid stacking carboys or using autoclave baskets with other objects on top
- Do not secure the openings of the carboy with aluminum foil, blue Steri-Wrap™ wrap, gauze, cotton, or tape
- Do not autoclave with the closure—**closure must be completely removed prior to autoclaving with no threads engaged**
- Wait until the closure and carboy are completely cooled to room temperature before securing closure
- If more than 1 L of liquid is in the carboy, it may take several hours or more to reach the target sterilization temperature (typically more practical to autoclave the carboy and sterilize liquid by in-line filtration directly into the container)
- A disposable carboy vent filter (Cat. No. 223-0030) is available featuring a hydrophobic, PTFE membrane, which permits sterile venting on slow exhaust/liquid autoclave cycles for the Nalgene PP and PC carboys up to 50 L; this vent filter can be used up to 5 times

# Polypropylene (PP) and polycarbonate (PC) sanitary fitting carboys

Perfect for use as supply reservoirs

- Easier to clean than threaded alternatives
- Autoclavable for in-house sterilization
- Round shape for homogeneity during stirring
- Graduations for volume determination at a glance
- PC is crystal-clear like glass
- PP has convenient shoulder handles for easy carrying



## Recommended applications

- Where cleaning validations are required
- For sterile transfers of product

Description	Capacity, L (gal)	Neck finish	Closure size, mm	Dimensions		No. per Pk/Cs	Cat. No.
				Width/OD, mm (in.)	Height with closure, mm (in.)		
PC Carboy	20 (5.3)	3 in. Tri Clover	—	287 (11.3)	498 (19.6)	1/4	2261-0050
PP Carboy	10 (2.6)	3 in. Tri Clover	—	250 (9.8)	353 (13.9)	1/1	2630-0010
PP Carboy	20 (5.3)	3 in. Tri Clover	—	282 (11.1)	496 (19.5)	1/1	2630-0020
PP Carboy	50 (13.2)	3 in. Tri Clover	—	379 (14.9)	545 (21.5)	1/1	2630-0050
PP Carboy with Sanitary Bottom Flange	10 (2.6)	—	83B, 1-1/2 in. Tri Clover	250 (9.8)	389 (15.3)	1/1	2640-0020
PP Carboy with Sanitary Bottom Flange	20 (5.3)	—	83B, 1-1/2 in. Tri Clover	282 (11.1)	526 (20.7)	1/1	2640-0050
PP Carboy with Sanitary Bottom Flange	50 (13.2)	—	83B, 1-1/2 in. Tri Clover	379 (14.9)	678 (26.7)	1/1	2640-0130
<b>Accessories</b>							
End Cap PP Loose 3/4 in.						1/1	2665-0075
End Cap PP Loose 3 in.						1/1	2665-0300
True Union Clamp PVDF Loose 3/4 in. Mini						1/1	2670-0075
True Union Clamp PVDF Loose 1 1/2 in.						1/1	2670-0150
True Union Clamp PVDF Loose 3 in.						1/1	2670-0300
Sanitary Gasket Platinum Cured Silicone 3/4 in. Mini						1/6	2672-0075
Sanitary Gasket Platinum Cured Silicone 1 1/2 in. Tri Clover						1/6	2672-0150
Sanitary Gasket Platinum Cured Silicone 3 in. Tri Clover						1/6	2672-0300
Heavy-Duty Clamp Stainless Steel 3 in.						1/1	2685-0300
3 in. Sanitary End Cap PC with two 3/4 in. Sanitary Flanges 3 in. Tri Clover						1/4	2688-2075
3 in. Sanitary End Cap PP with two 3/4 in. Sanitary Flanges 3 in. Tri Clover						1/4	2689-2075

# Regulatory compliance and customer support

We understand the importance of our customers' critical applications. That's why our containers are manufactured in compliance with rigorous quality systems, offering traceability and controls from raw materials through the finished product.

We make it our mission to support our customers' regulated high-value applications with:

- ISO 13485:2003 and GMP Class I certified manufacturing systems
- Resin and product validation data support

## Manufacturing certifications

In 2003, the Thermo Fisher Scientific manufacturing facilities in Rochester and Fairport, New York achieved ISO 13485 compliance. This upgrade superseded the ISO 9001 system that was in place since May 1995. Both sites are also registered as GMP (Good Manufacturing Practices) facilities for Class I devices (design exempt) with the US Food and Drug Administration. In addition, many of the GMP practices are extended to Nalgene bottle manufacturing, even though the Nalgene bottles themselves are not registered medical devices.

## Resin and product validation data

Most of our resins are DMF-registered by the supplier and meet a number of regulatory specifications including USP Class VI, EP monographs and EU food-contact directives, CONEG, RoHS, CA Prop 65, SARA Title III Sec. 313, and 21 CFR pt 177. Most Nalgene resins are free from ADCs, BPA, phthalates, and contact with latex. Compliance statements by catalog number are available by contacting Regulatory Support.

A validation binder containing compliance data and product specifications is available to customers, provided they have a signed confidentiality agreement. For additional information, contact our Regulatory Support team at [rocregsupport@thermofisher.com](mailto:rocregsupport@thermofisher.com).

- Lot-specific product certificates on demand
- Change control procedures
- Change notification services and support
- Customer onsite audits by appointment

## Certificates on demand

Customers can receive a lot-specific Nalgene product certificate on demand at any time, day or night, from our website.

Enter the lot number in the field at the bottom of each product webpage, and a PDF of the certificate is delivered instantly for print or download.

## Change control procedures

In accordance with ISO and GMP requirements, changes to manufacturing procedures, packaging, and product specifications require methods following specific documented processes for approval and implementation. All changes are documented and traceable.

## Customer notification services

Customers can receive electronic notification of changes to product form, fit, function, manufacturing location, tooling, and major process changes by registering in our customer change notification database. Register for change notifications for a specific list of Nalgene items at [thermofisher.com/registercustomernotifications](https://thermofisher.com/registercustomernotifications)

# Low-density polyethylene (LDPE)

A high-quality option for everyday use

- Leakproof PP screw-top design
- Convenient shoulder handles for easy carrying and pouring
- Graduations for volume determination at a glance
- Wide-mouth version for easy cleaning, filling, and dispensing
- Round for homogeneity during stirring



## Recommended applications

- Light-duty applications
- Stirring and storage of intermediates

Description	Capacity, L (gal)	Closure Size, mm	Dimensions		No. per Pk/Cs	Cat. No.
			OD, mm (in.)	Height with Closure, mm (in.)		
Carboy with Handles	10 (2.6)	83B	250 (9.8)	389 (15.3)	1/6	2210-0020
Carboy with Handles	15 (3.8)	83B	285 (11.2)	429 (16.9)	1/4	2210-0040
Carboy with Handles	20 (5.3)	83B	282 (11.1)	526 (20.7)	1/4	2210-0050
Carboy with Handles	25 (6.5)	83B	287 (11.3)	594 (23.4)	1/4	2210-0065
Carboy with Handles	50 (13.2)	83B	379 (14.9)	668 (26.3)	1/1	2210-0130
Wide-Mouth Carboy with Handles	10 (2.6)	100-415	250 (9.8)	343 (13.5)	1/6	2234-0020
Wide-Mouth Carboy with Handles	15 (3.8)	100-415	286 (11.3)	389 (15.3)	1/6	2234-0030
Wide-Mouth Carboy with Handles	20 (5.3)	100-415	282 (11.1)	483 (19.0)	1/4	2234-0050
<b>Accessories</b>						
83B Replacement Closure for Large Nalgene Bottles or Carboys					2/2	712160-0830



## Quality control, testing, and inspection

Nalgene containers are subjected to rigorous scrutiny prior to their release

### Resin inspection

Checks are performed on incoming lots of resin material as noted below. All tests are based on Nalgene container historical data and information supplied by our resin manufacturers.

**Resin flow:** Melt flow indexes are performed on selected lots of incoming resin per ASTM D1238.

**Visuals:** A visual comparison of each lot of resin is performed to assure that there is limited lot-to-lot color variation during manufacturing runs. Granular size and configuration of each lot is also checked to ensure that uniform molding will be accomplished.

### Molding inspection

Molding inspection is performed in two major steps. Step one is the first piece approval stage. Manufacturing must obtain first piece approval from Quality Control before any parts can be assigned to stock.

Step two is the critical in-process inspection. Parts are continually checked at specific intervals during the entire production run. We perform a standard Nalgene container leak test, and parts are inspected for:

- Physical defects/appearance
- Molding integrity/completeness of threads and sealing ring (closure)
- Dimensions

### Our leakproof testing procedures

Containers and closures are tested separately with water. The term “leakproof” applies to products that meet the following criteria:

1. Carboy/closure systems with closures smaller than 100 mm are filled with water and set on their side, and air pressure of 2 psig for 2 minutes is applied. The test is successful when no water escapes.
2. Carboy/closure systems with closures of 100 mm or larger are filled with water and inverted, and are allowed to stand for 15 minutes. The test is successful when no water escapes.

These tests using other liquids may not yield the same results. To ensure safe usage, we recommend testing with your specific combination of container/closure/contained material.

**Warning:** Do not use Nalgene carboys or other containers under pressure or vacuum, except those products that are specifically designed, specified, and tested for these conditions. The application of pressure or vacuum to products not designed for such use may result in failure of the products, damage to property, and/or personal injury.

# Supporting resin information

Refer to the tables on the following pages for resin properties, torque recommendations for our caps and chemical resistance.

## Resin quick reference chart

	PP	PPCO	LDPE	HDPE	PC	PMP	PETG	FEP	PFA	ETFE
High Temperature	135°C	121°C	80°C	120°C	135°C	145°C	70°C	205°C	260°C	150°C
Low Temperature	0°C	-40°C	-100°C	-100°C	-135°C	20°C	-40°C	-270°C	-270°C	-105°C
Autoclavable	Y	Y	N	N	Y	Y	N	Y	Y	Y
Microwaveable	Y	Marginal	Y	N	Marginal	Y	Marginal	Marginal	Y	Y
Dry Heat (Oven)	N	N	N	N	Y	Y	N	Y	Y	Y
Freeze	N	Y	Y	Y	Y	N	Y	Y	Y	Y
Flexibility	Rigid	Moderate	Excellent	Moderate	Rigid	Rigid	Moderate	Excellent	Excellent	Rigid
Clarity	Translucent	Translucent	Translucent	Translucent	Clear	Clear	Clear	Translucent	Nearly Clear	Translucent
Chemical Resistance	Good	Good	Good	Good	Minimal	Good	Minimal	Excellent	Excellent	Excellent
Recycling Symbol	 PP	 PP	 LDPE	 HDPE	 OTHER	 OTHER	 PETE	 OTHER	 OTHER	 OTHER

## Resin Codes

- ETFE: ethylene-tetrafluoroethylene
- FEP: fluorinated ethylene propylene
- FLPE: fluorinated high-density polyethylene
- HDPE: high-density polyethylene
- LDPE: low-density polyethylene
- PC: polycarbonate
- PETG: polyethylene terephthalate glycol
- PFA: perfluoroalkoxy
- PMP: polymethylpentene ("TPX")
- PP: polypropylene
- PPCO: polypropylene copolymer
- TPE: thermoplastic elastomer

## Resin properties

Resin	Max use temp <sup>1</sup> (°C)	HDT <sup>2</sup> temp. (°C)	Brittleness <sup>3</sup> Temp. (°C)	Transparency	Sterilization <sup>5</sup>								Permeability (cc-mil/100 in <sup>2</sup> -24 hr.-atm)		
					Micro-wave-ability	Auto-claving	Gas	Dry heat	Radiation	Disinfectants	Specific gravity	Flexibility	N	O	CO
LDPE	80	45	-100	Translucent	Yes	No	Yes	No	Yes	Yes	0.92	Excellent	180	500	2,700
HDPE	120	65	-100	Translucent	No	No	Yes	No	Yes	Yes	0.95	Rigid	42	185	580
PP	135	107	0	Translucent	Yes	Yes	Yes	No	No	Yes	0.9	Rigid	48	240	800
PPCO	121	90	-40	Translucent	Marginal <sup>4</sup>	Yes	Yes	No	No	Yes	0.9	Moderate	45	200	650
PMP	145	80	20	Clear	Yes	Yes	Yes	Yes	No	Yes	0.83	Rigid	8,000	32,000	115,000
FLPE	120	65	-100	Translucent	No	No	Yes	No	Yes	Yes	0.95	Rigid	42	185	580
ETFE	150	104	-105	Translucent	Yes	Yes	Yes	Yes	Yes	Yes	1.7	Rigid	30	100	250
FEP	205	70	-270	Translucent	Marginal <sup>4</sup>	Yes	Yes	Yes	No	Yes	2.15	Excellent	320	750	2,200
PFA	260	166	-270	Translucent	Yes	Yes	Yes	Yes	No	Yes	2.15	Excellent	291	881	2,260
PETG	70	70	-40	Clear	Marginal <sup>4</sup>	No	Yes	No	Yes	Some	1.27	Moderate	10	25	125
PC	135	138	-135	Clear	Marginal <sup>4</sup>	Yes <sup>6</sup>	Yes	No	Yes	Yes	1.2	Rigid	50	300	1,075
TPE	121	<23	<-50	Opaque	Yes	Yes	Yes	No	Yes	Some	0.93	Excellent	31-145	85-646	900-8,634

## Resin properties (continued)

Resin	Permeability (cc.-mm/m <sup>2</sup> -24hr.-Bar)			Water vapor transmission rate (g-mm/m <sup>2</sup> 24 hr.-Bar at 38°C, 90% RH)	Water adsorption (%)	Non-cyto-toxic <sup>7</sup>	Suitable for food and bev. use <sup>8</sup>	Part 21 CFR	Refractive index	Melting point range (°C)	Glass transition temperature range (°C)
	N	O	CO								
LDPE	69.94	154.28	1,049.09	15.5-23.3	<0.01	Yes	Yes <sup>9</sup>	177.1520	1.5400	85 to 125	-25
HDPE	16.32	71.88	225.36	4.6-6.2	<0.01	Yes	Yes <sup>9</sup>	177.1520	1.5100	125 to 138	-25
PP	18.65	93.25	310.84	3.9	<0.02	Yes	Yes	177.1520	1.4735	160 to 176	-20 to -5
PPCO	17.48	77.71	252.56	4.40	<0.02	Yes	Yes	177.1520	1.4735-1.5100	150 to 175	-20
PMP	3,109.42	12,433.68	44,683.32	775	0.01	Yes	No	—	1.4630	235	N/A
FLPE	16.32	71.88	225.36	4.6	<0.01	Yes	Yes <sup>9</sup>	177.1615	1.5100	125-138	-125
ETFE	11.66	38.86	97.14	1.65	0.03	Yes	Yes	177.1550	1.3580	265	N/A
FEP	124.34	291.41	854.82	6.20	<0.01	Yes	Yes	177.1550	1.3380	275	N/A
PFA	118.07	342.31	878.13	2.00	<0.02	Yes	Yes	177.1550	1.3580	302 to 310	N/A
PETG	3.89	9.71	48.57	18.13	0.13	Yes	Yes <sup>10</sup>	177.1315	1.57	265	81
PC	19.43	116.57	417.69	115	0.35	Yes	Yes	177.1580	1.5860	N/A	154
TPE	12.05-56.34	33.03-251	0.70-3,354.76	—	0.05-5.1	Yes	Yes	177.2600	—	N/A	N/A

- Ratings based on 5-minute tests using 600 watts of power on exposed, empty labware. CAUTION: Do not exceed Max. Use Temp., or expose labware to chemicals where heating causes them to attack the plastic or be rapidly absorbed.
- Heat deflection temperature is the temperature at which a bar deflects 0.01 in. at 66 psig (ASTM D648). Materials may be used above their heat deflection temperatures in non-stress applications; see maximum use temperature.
- The brittleness temperature is the temperature at which an item made from the resin may break or crack if dropped. This is not the lowest use temperature if care is exercised in use and handling.
- Plastic will absorb heat.
- Sterilization:
  - Autoclaving (121°C, 15 psig for 20 minutes)—clean and rinse items with distilled water before autoclaving. (Always completely disengage thread before autoclaving.) Certain chemicals that have no appreciable effect on resins at room temperature may cause deterioration at autoclaving temperatures unless removed with distilled water beforehand
  - Gas—Ethylene oxide, formaldehyde, hydrogen peroxide
  - Dry heat (160°C, 120 minutes)
  - Disinfectants—benzalkonium chloride, formalin/formaldehyde, ethanol, etc.
  - Radiation—gamma irradiation at 25 kGy (2.5 Mrad) with unstabilized plastic
- Autoclaving reduces mechanical strength. Do not use PC vessels for vacuum applications if they have been autoclaved.
- "Yes" indicates the resin has been determined to be non-cytotoxic, based on USP and ASTM biocompatibility testing standards utilizing a MEM elution technique on a WI38 human diploid lung cell line.
- Resins meet requirements of Part 21 CFR section of Food Additives Amendment of the Federal Food and Drug Act. End users are responsible for validation of compliance for specific containers used in conjunction with their particular packaging applications.
- Acceptable for:
  - Nonacid, aqueous products; may contain salt, sugar, or both (pH above 5.0)
  - Dairy products and modifications; oil-in-water emulsions, high or low fat
  - Moist bakery products with surface containing no free fat or oil
  - Dry solids with the surfaces containing no free fat or oil (no end-test required) and under all conditions as described in Table 2 of FDA Regulation 177.1520 except condition A—high temperature sterilization (e.g. over 100°C/212°F)
- Acceptable for:
  - Alcoholic foods containing not more than 15% (by volume) alcohol; fill and storage temperature not to exceed 49°C (120°F)
  - Non-alcoholic foods of hot fill to not exceed 82°C (180°F) and 49°C (120°F) in storage
  - Not suitable for carbonated beverages or beer or packaging food requiring thermal processing

# Chemical resistance classification

Refer to the data below to ensure proper carboy selection for your specific applications.

	ETFE	FLPE	HDPE	LDPE	PC	PETG	FEP/ PFA	PMP	PP/ PPCO	TPE*
Acids, dilute or weak	E	E	E	E	E	G	E	E	E	G
Acids, strong and concentrated**	E	G	G	G	N	N	E	E	G	F
Alcohols, aliphatic	E	E	E	E	G	G	E	E	E	E
Aldehydes	E	G	G	G	F	G	E	G	G	G
Bases/alkali	E	F	E	E	N	N	E	E	E	F
Esters	G	G	G	G	N	F	E	E	G	N
Hydrocarbons, aliphatic	E	E	G	F	G	G	E	G	G	E
Hydrocarbons, aromatic	G	E	N	N	N	N	E	N	N	N
Hydrocarbons, halogenated	G	G	N	N	N	N	E	N	N	F
Ketones, aromatic	G	G	N	N	N	N	E	F	N	N
Oxidizing agents, strong	E	F	F	F	F	F	E	G	F	N

\* TPE gaskets.

\*\* Except for oxidizing acids: for oxidizing acids, see "Oxidizing Agents, strong."

## Chemical resistance classification

**E:** 30 days of constant exposure causes no damage. Plastic may even tolerate exposure for years.

**G:** Little or no damage after 30 days of constant exposure to the reagent.

**F:** Some effect after 7 days of constant exposure to the reagent. Depending on the plastic, the effect may be crazing, cracking, loss of strength, or discoloration. Solvents may cause softening, swelling, and permeation losses with LDPE, HDPE, PP, PPCO, and PMP. The solvent effects on these five resins are normally reversible; the part will usually return to its normal condition after evaporation.

**N:** Not recommended for continuous use. Immediate damage may occur. Depending on the plastic, the effect will be a more severe crazing, cracking, loss of strength, discoloration, deformation, dissolution, or permeation loss.

This information is only a summary. Access our chemical resistance database at

[thermofisher.com/chemicalresistance](https://thermofisher.com/chemicalresistance)



# Torque recommendations

Torque must be properly applied in measured amounts to Nalgene closures to assure leakproof sealing. To maintain the closure/carboy seal and minimize back-off during shipment, Nalgene closures should be tightly applied using the guidelines provided.

Because different applications will require different torques for the same closure/bottle system, it is recommended that users determine these values on their own filling and capping lines. With automatic capping machines, application torque must be correlated to removal torque using torque wrenches.\*

**Note:** Carboy and closure threads must be dry when torque is applied to the system.

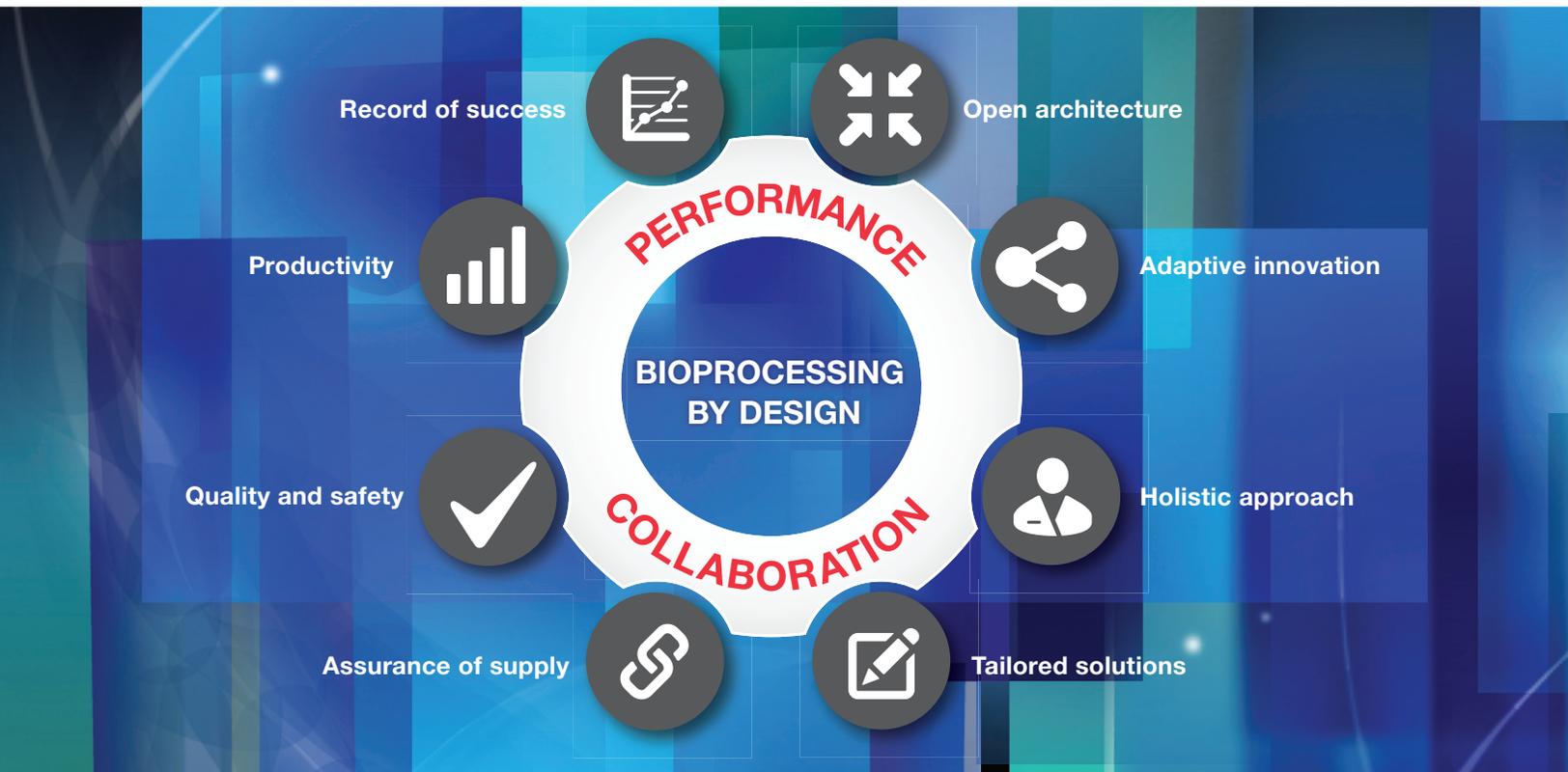
## Recommended application torques for Nalgene closures

Closure Size, mm	Minimum Torque		Maximum Torque**	
	in.-lb.	1cm-kg	in.-lb.	1cm-kg
11	2	3	3	4
13-415	5	6	7	8
20-415	10	11	14	16
24-415	12	13	17	19
28-415	16	18	22	25
33-415	20	23	28	32
38†	27	31	33	38
38-415	22	25	31	38
38-430	27	31	33	38
43-415	28	32	39	44
48-415	30	34	42	48
48†	30	34	42	48
53-415	33	38	46	52
53B	38	43	53	60
63-415	40	46	56	64
70	44	50	62	71
83B	60	69	84	96

\* For details, refer to the Handbook of Package Engineering, Third Edition by Joseph F. Hanlon.

\*\* This number should not be exceeded. It is strongly recommended that users verify these torque numbers, based on their applications. For more information, contact technical support.

† Thermo Scientific™ Nalgene™ Biotainer™ container closures



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To meet the increasing demand for biologics worldwide, you need to expect more from suppliers. It isn't just about the products we deliver, but how we do business together.

With a collaborative approach that is grounded in our technical knowledge, we work with you to achieve optimal bioprocessing outcomes. Committed to identifying the technologies and services that address your needs, from drug development through large-scale commercial production, we provide integrated and tailored solutions that improve the overall biomanufacturing experience. If a solution doesn't exist, we'll build it—together.

And while we are flexible in our approach, we are uncompromising in our pursuit of performance. Through technical engagement, innovative product design, and strategic sourcing programs, we deliver productivity, quality, and assurance of supply so that you can have complete confidence in the efficiency and speed of your biologics development and manufacturing processes.

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